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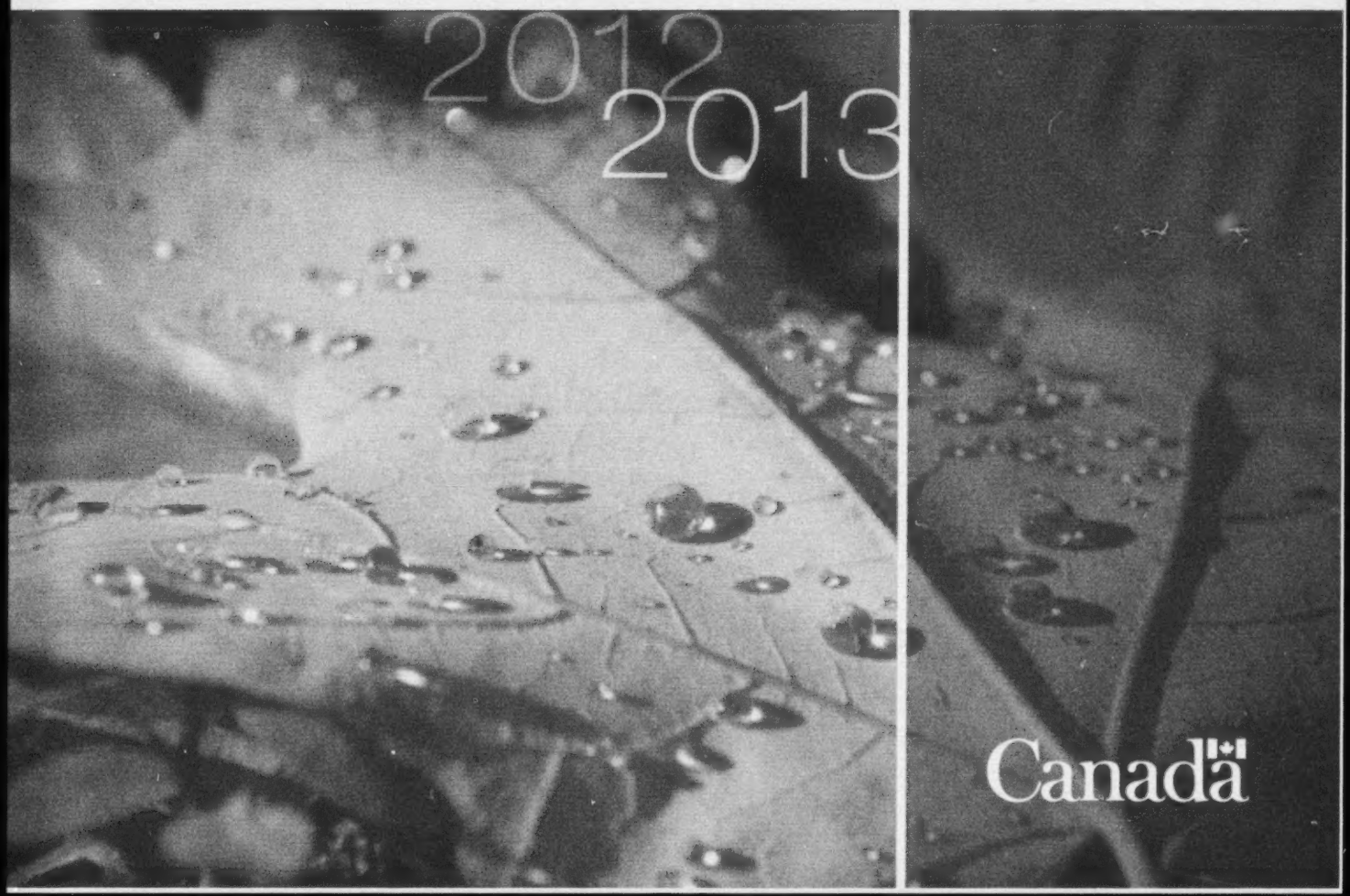
Pest Management Regulatory Agency

Annual Report 2012–2013



Également offert en français sous le titre :
Agence de réglementation
de la lutte antiparasitaire
Rapport annuel
2012–2013

This publication is also available on the Internet at healthcanada.gc.ca/pmra

This publication can also be made available in alternate format(s) upon request.

The Pest Management Regulatory Agency publications team was responsible for the translation, formatting and publication of this document.

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ISSN: 1719-2358 (PDF version)
Catalogue Number: H110-2012E-PDF (PDF version)

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Executive Summary

The Health Canada Pest Management Regulatory Agency (PMRA) is pleased to present the 2012–2013 Annual Report to Parliament, which details the PMRA's accomplishments and activities over the past fiscal year. In 2012–2013, the PMRA registered 27 new active ingredients, resulting in the registration of 34 new end-use products. As of 31 March 2013, 13 new active ingredients were under joint review with other jurisdictions. Re-evaluation of older products on a 15-year cycle continued, with 11 re-evaluations completed and 22 initiated this fiscal year. The PMRA continues to increase its international involvement in pesticide regulation through joint reviews, workshares, scientific developments, and international working groups. In 2012–2013 considerable effort was put toward addressing issues related to pollinator declines, working with stakeholders, scientists and regulatory counterparts provincially, nationally and internationally.

Vision, Mission and About the PMRA

Vision

Continually promoting the highest standards for the protection of health and the environment, based on modern science, Health Canada has been an international force in the regulation of pesticides resulting in public confidence and improved access to safer and innovative pesticides for Canadians. The PMRA has invested in its workforce, workplace and partnerships to support one of the best pesticide regulatory systems in the world.

Mission

Protecting the health and the environment of Canadians and supporting Canadian competitiveness by regulating pesticides and their use in an effective and transparent manner.

About the PMRA

The PMRA is a branch of Health Canada and is responsible for regulating pest control products under the federal authority of the *Pest Control Products Act*. Our mandate is to prevent unacceptable risks to people and the environment from the use of these products. We also encourage the development and application of sustainable pest management strategies and facilitate access to lower risk pest control products. We use modern scientific assessment techniques to assess human and environmental health risks when evaluating and re-evaluating pest control products. The PMRA endeavours to address public and stakeholder concerns, as well as to develop mechanisms to facilitate access to new innovative products.

Core Regulatory Activities:
Protecting Canada, Protecting Canadians

Before a pesticide can be sold in Canada, pesticide registrants are required to provide the PMRA with large volumes of data to show that their product does not pose unacceptable risks to health and the environment and that the product has value. These data are reviewed by PMRA scientists to determine whether a product is acceptable for registration in Canada. Developing a pesticide for use in the global marketplace can take several years and can cost manufacturers millions of dollars.

The PMRA's science-based risk assessment includes the following:

- an examination of all sources and routes (oral, dermal, inhalation) of potential exposure to a given pesticide, including exposure through diet, from drinking water and from contact with treated areas like lawns and gardens;
- an estimation of the amount of pesticides that people, including children, may come in contact with, both during and after a pesticide application;
- a human health risk assessment based on the toxicity in relation to the amount of exposure in all potentially exposed special populations, including children; and considers the potential for a pesticide to cause adverse health effects such as cancer, birth defects and endocrine disruption;
- an assessment of the fate and behavior of a pesticide in the environment;
- an environmental risk assessment that considers risks to plants, birds, mammals, beneficial insects, aquatic organisms as well as fate in the environment; and
- a value assessment that considers the contribution of the product to pest management, as well as its health, safety and environmental benefits, and social and economic impact.

Science is continually evolving, and pesticide regulation is becoming an increasingly global activity. The PMRA responds to these changes by incorporating scientific evaluation methods that meet the most modern standards, adapting regulations and registration processes to accommodate new pest management approaches, and playing an important role in the development and execution of international regulatory cooperation.

New Registrations

Products that meet the PMRA's health and environmental requirements, and are shown to have value, are registered for use in Canada under the conditions stated on the label. There are different types of registered products, including agricultural (food and non-food), industrial and domestic products, and products that can only be applied by licensed professionals. The PMRA is shifting towards conducting more product reviews in collaboration with other countries. This creates efficiencies in product evaluations, and increases access to important innovative products that may not otherwise be registered in Canada.

New Active Ingredients Registered in 2012–2013

In 2012–2013, 27 new active ingredients were registered for use in Canada, resulting in the registration of 34 new end-use products. Of the 27 new active ingredients, 14 were biopesticides, 11 were conventional pesticides and 2 were antimicrobials. Please see the Appendix, Table 1, for a full list of new active ingredients registered, and their uses.

Joint Reviews

As of 31 March 2013, 13 new active ingredients were under joint review, including 5 conventional chemicals under global joint review. In addition, there were two new proposals for the global joint review of new conventional chemical active ingredients pending applications for registration from industry.

Generic Registrations

Regulatory provisions for the protection of test data are intended to advance the availability of modern, innovative, potentially lower-risk products to Canadian users by facilitating the timely entry of competitively priced generic pesticides, while encouraging the introduction of new pesticides by protecting the innovator's substantial investment in a supporting database.

In 2012–13, 35 generic products were registered, including 21 technical or manufacturing products and 14 end-use products. Key active ingredient generics registered for agriculture include florasulam, fluroxypyr, glufosinate ammonium, glyphosate, imidacloprid and metribuzin.

Minor Uses

The PMRA regularly meets with Agriculture and Agri-Food Canada's Pest Management Centre to provide regulatory advice that helps in encouraging the participation from growers and grower associations in a collaborative process to identify priorities for new minor uses in Canada. The Canada-U.S. Grower Priority Database is an important tool to support grower-requested priority reviews in both countries. In 2012–2013, 130 regulatory decisions were made resulting in 586 new minor uses registered, of which 20 were joint reviews or workshares.

Registration Process Improvements

The PMRA is continually seeking ways to make the management of pesticide submissions more efficient, effective, and predictable for applicants/registrants and the PMRA, while continuing to protect the health and environment of Canadians.

The PMRA continued to identify opportunities for improvements to the Management of Submission Policy. Internal timelines were adjusted to better reflect the level of effort required to complete them. Progress was also made toward closer alignment of registration processes with approaches used by regulatory authorities in other jurisdictions. This included work on the Notification Process, Statement of Product Specifications Form and Data Code Tables. This work will facilitate workshares and joint reviews.

All of these registration process improvements will be supported through updates to the Pesticides and Pest Management section of Health Canada's website and the electronic Pesticide Registration System (ePRS). The ePRS has been updated to more clearly track data ownership and its use in various submissions, which will help the PMRA develop compensable lists for data protection purposes. The website has been updated with new Web Compliance and Accessibility Guidelines (WCAG 2.0) forms. These forms can be completed online, and can be downloaded in Word format for submission to the PMRA.

Emergency Registrations

A pest control product can be registered for up to one year for the emergency control of pest infestations for which no other effective method of control exists. The product must be effective, and the human health and environmental risks must be acceptable.

Emergency registrations are not intended as a solution to an ongoing pest management problem. However, they may be reconsidered if the emergency situation exists in subsequent years and there is evidence that users and the sponsoring agencies are actively working towards satisfying the data requirements for registration.

The number of emergency requests that the PMRA receives can vary from year to year, depending on pest outbreaks, environmental conditions and the availability of alternative products and methods. In the 2012–2013 fiscal year, the PMRA granted 28 emergency registrations, of which six were new requests.

Regulatory Cooperation Council (RCC)

In 2012–2013, the PMRA led or participated in several initiatives under the Canada-United States Regulatory Cooperation Council (RCC). The RCC joint action plan sets out four action items where Canada and the United States will seek greater alignment in their regulatory approaches: by encouraging joint submissions of use expansion and fully aligned labels, developing joint guidelines for residue trials, addressing obstacles to joint registration and aligning the data collection procedures for residue trials. The aim of the RCC is to progress from work sharing to mutually accepting and exchanging reviews between the two countries.

The PMRA continues working towards this goal by collaborating on an ongoing basis on several initiatives including:

- Pesticide Joint Review Program
- Aligned labels
- A completed pilot to encourage joint minor use label expansions concurrent with submissions for import Maximum Residue Limits (MRLs)/tolerances
- North American Free Trade Agreement (NAFTA) Label Program
- Development of a common Product Chemistry Specification Form
- Aligned submission review timelines for joint reviews
- Routine participation in joint work planning meetings with industry
- Development of a common Information Technology (IT) strategy
- Exploration of opportunities to exchange and accept residue trial data
- Exploration of opportunities to accept data generated in each country (residue trials)

Scientific Developments

The PMRA continues to collaborate on an ongoing basis with other government departments, Canadian provinces/territories, the United States Environmental Protection Agency (USEPA), and through North American Free Trade Agreement and Organisation for Economic Co-operation and Development (OECD) working groups on several initiatives.

Integrated Approaches to Testing and Assessment

Pesticide regulatory agencies have traditionally relied on extensive in vivo and in vitro testing to support regulatory decisions on human health and environmental risks. While this approach has provided strong support for risk management decisions, there is a clear recognition that even with the significant amounts of information from standard testing approaches, pesticide regulators are often faced with questions and issues relating to modes of action for toxicity, novel toxicities, susceptible populations, and other factors that can be challenging to address using traditional approaches.

Recognizing the limitations of current testing approaches and the rapid development of new biochemical and cellular assay systems and computational predictive methods, pesticide and other regulatory agencies have initiated an investigation of Integrated Approaches to Testing and Assessment (IATA).

The PMRA and the United States Environmental Protection Agency Office of Pesticide Programs (USEPA/OPP) have cooperated on the development of a guidance document on the use of Quantitative Structure Activity Relationships ([Q]SAR) for pesticide risk assessors. [Q]SAR is an important set of predictive tools that can be considered when applying IATA to pesticide assessments. This document has been developed under a North American Free Trade Agreement Technical Working Group project, 21st Century Toxicology: Integrated Approaches to Testing and Assessment and is currently available for download from the USEPA/OPP website.

OECD Harmonized International Guidance for Pesticide Terrestrial Field Dissipation Studies and Crosswalk of North American and European Eco-regions

Terrestrial field dissipation data, which help determine fate and behaviour of pesticides under actual use conditions when the pesticides are used according to label directions, are required worldwide for pesticide registration. Studies conducted in different countries are often submitted for consideration for Canadian review as well as global joint reviews. To consider these foreign studies, the environmental conditions of the study site, the ecoregion where the study was done, must be similar to Canada.

The PMRA, in collaboration with Agriculture and Agri-food Canada, USEPA and European Union organizations such as the European Food Safety Organization and the European Union Joint Research Centre, is developing a method to identify comparable ecoregions between North America and Europe. This Geographic Information System-based model would allow a terrestrial field dissipation study conducted in Europe to be used by North American regulators and vice versa for their respective regulatory reviews. The PMRA and the USEPA are also developing harmonized terrestrial field dissipation study guidance acceptable to all organizations

Environmental Loading of Hexachlorobenzene

In 2012–2013, a project was undertaken to examine PMRA's progress in reducing the environmental loading of hexacholorobenzene (HCB) from agricultural pesticides in accordance with the Toxic Substances Management Policy (TSMP). The results showed a significant reduction in releases from 2008 to 2010 (41.7 kg to 13.6 kg) which was the result of contaminant reduction strategies, re-evaluation decisions and the market shift toward newer/cleaner chemistries. The PMRA approach to tracking and implementing reduction efforts by targeting the major contributors are being applied to other pesticide contaminants slated for virtual elimination.

Pollinators

In the spring of 2012, a large number of incidents of bee mortality potentially related to pesticide exposure were reported in Ontario and Quebec. The timing of incidents correlated with corn planting. The PMRA worked with the Ontario Ministry of Agriculture and Food and the Ontario Ministry of the Environment to investigate these incidents and evaluate the role pesticides may have played in these bee losses.

This involved responding to 41 beekeepers, analyzing 195 samples (bees, pollen, seeds and vegetation), and conducting 39 investigations. In addition, seven intensive agricultural surveys were also conducted to compile and assess agricultural information related to the incidents. It was concluded that most of the incidents were related to exposure of pollinators to the insecticide-contaminated dust generated during planting of corn seed treated with neonicotinoid pesticides.

The PMRA continued its efforts to help reduce risks to pollinators by developing and communicating best management practices to minimize pollinator exposures. The PMRA also worked closely with growers, beekeepers, seed-treatment facilities, seeding equipment manufacturers and the pesticide industry to develop strategies to further protect bees from exposure to dust generated during planting of treated seed. Health Canada also initiated a re-evaluation of the neonicotinoid insecticides in collaboration with the USEPA.

Health Canada scientists continue to work with scientists from other organizations (Universities, Agriculture and Agri-food Canada, provincial ministries of agriculture and environment, Canadian Association of Apiculturists, and other regulatory agencies in the United States and Europe) to determine if neonicotinoid pesticides are contributing to pollinator declines.

Pollinator activities are coordinated internationally through the activities of a number of international working groups. The OECD Working Group on Pesticides: Pesticide Effects on Insects Pollinators is co-led by Canada and the United States and provides a venue for communication of pollinator incidents, development of pollinator testing requirements and assessments, developing mitigating strategies for pollinator risks and the maintenance of a pollinator research database. Through the OECD Working Group of the National Coordinators on the Test Guidelines Program, Health Canada has contributed to the development of honey bee larvae toxicity study protocols. Health Canada also contributes to the International Commission for Plant-Bee Relationships through which the risks posed by seed treatment dust and guttation water are examined and guidance is being developed for study protocols for field and semi-field studies, monitoring studies as well as larvae/brood studies. Health Canada has collaborated with the US EPA and the California Department of Pesticide Regulation to develop a North American Pollinator Risk Assessment Framework with the help of a Pollinator Science Advisory Panel. Health Canada also participates on the USEPA Pesticide Program Dialogue Committee Working Group on Pollinator Protection where risk mitigation is addressed through labeling and best management practices.

Post-Market Activities

After pesticides are registered, several mechanisms are in place to monitor products under real-world use conditions, and to identify and mitigate unexpected risks.

Re-Evaluation Program

Under the *Pest Control Products Act*, re-evaluations of pesticide registration decisions are initiated at a minimum every 15 years. Regulatory Directive DIR2012-02, Re-evaluation Program Cyclical Re-evaluation, outlines the process being followed to consider any changes in the information required, or to the procedures used, to evaluate the health and environmental risk or value since the last major regulatory decision on a pesticide or group of pesticides. This helps to ensure that registered pesticides continue to meet modern standards for health and environmental protection.

During fiscal year 2012–2013, 22 re-evaluations were initiated in accordance with the *Pest Control Products Act* and of these, 11 re-evaluation project plans were published to outline the focus of the work underway. Of particular note was the initiation of two nitro-guanidine neonicotinoid insecticides, clothianidin and thiamethoxam, and their associated products, which are being grouped with imidacloprid, a third insecticide in this family that was already under re-evaluation. The re-evaluation of this cluster of pesticides will focus on resolving issues related to environmental risk—in particular, the potential for effects of nitro-guanidine neonicotinoids on pollinators, in light of changes to the information required and global updates to the pollinator risk assessment framework.

Also during fiscal year 2012–2013, 11 re-evaluations were completed with final decision documents published, resulting in amended product use conditions on approximately 276 end-use products to further protect human health and the environment. Please see the Appendix, Table 2, for a list of re-evaluation decisions.

Chemicals Management Plan

Under the Government of Canada's Chemicals Management Plan, the PMRA continues to collaborate with other government departments in the evaluation and risk management of chemical substances in Canada. For more information, please consult the Chemicals Management Plan webpage: www.chemicalsubstanceschimiques.gc.ca/plan/index_e.html.

National Compliance Program

Compliance activities, conducted in collaboration with federal and provincial partners, include compliance promotion and monitoring inspection programs. These activities are an important mechanism for post-registration pesticide-risk reduction.

In 2012–2013, in accordance with the *Pest Control Products Act*, PMRA delivered 26 compliance programs targeting users, distributors, importers, vendors, registrants, manufacturers and formulators. Approximately 840 program inspections were conducted to verify compliance with the *Pest Control Products Act*. Most of these inspections detected high levels of compliance. Situations of non-compliance were reviewed, resulting in applicable enforcement actions.

Twenty-three independent surveillance inspections were conducted on previous high-risk compliance violators. While the results of one inspection await lab results, 15 of the other 22 of the violators (68%) have returned to full compliance. A total of 681 samples were submitted to the PMRA laboratory for analysis, 370 of which were collected during inspections.

Furthermore, following the spring 2012 incidents of bee mortality in Ontario, the PMRA responded to 41 complaints, analyzed 195 samples (bees, pollen, seeds and vegetation), and administered 33 agricultural questionnaires, with an additional six investigations completed on our behalf by the Ministry of the Environment.

Under the Food and Consumer Safety Action Plan, the PMRA conducted a total of nine active prevention and inspection programs and projects in several areas, including rental properties, customs brokers, and personal insect repellents.

Finally, Health Canada carried out approximately 1300 enforcement responses, aimed at correcting non-compliance within the regulated community, ranging from label modifications, denials of entry at the border, seizures and detentions to compliance orders, enforcement letters and Administrative Monetary Penalties.

Outreach Activities

The PMRA's outreach program has three main functions: to develop and distribute material to professional and consumer audiences on all aspects of responsible pesticide use; manage a 1-800 information line and e-mail service to respond to enquiries on pesticides and pest management; and to provide support and advice for regional office participation at fairs, exhibits and other opportunities through the use of displays, didactic tools and printed material.

Working closely with the scientific teams of the PMRA, the outreach team produced and disseminated materials responding to current and emerging needs. Of particular note this past year, the PMRA produced a factsheet on responsible pesticide use for landlords and building managers. The Pest Management Information Service responded to over 1650 calls and e-mails from the public on a broad range of questions relevant to pest management and responsible pesticide use. Regional compliance offices were supplied with exhibit material designed to engage the public in discussion about consumer pesticide products, and more specialized audiences such as grower groups and provincial partners.

Financial Profile

Financial Profile (in millions of dollars)

A-base (including the Food and Consumer Safety Action Plan)	$34.1M
Revenue	$7.9M
Growing Forward	$3.7M
CMP	$5.0M
Total	**$44.9M**

The PMRA received $3.7M through the Growing Forward initiative to support the registration of minor use products. As a result, newer, more environmentally sustainable, and more modern, products have been made available to Canadian producers, which helps sustain Canada's competitive position globally.

Through Canada's Chemicals Management Plan, the PMRA is receiving $25M over fiscal years 2011–2012 to 2015–2016 to re-evaluate older pesticides, improve risk-management approaches through Incident Reporting and Sales Reporting regulations, and contribute to the development of scientific and regulatory approaches with other jurisdictions on high-priority issues.

The PMRA received $13.2M for the Canada Food and Consumer Safety Action Plan over fiscal years 2008–2009 to 2012–2013. This plan encouraged and facilitated industry quality assurance and stewardship programs for the safe manufacture, selection and use of consumer pesticide products. These funds were also used to enhance targeted oversight by increasing compliance-enforcement capacity to increase public confidence in pesticide product safety and increase rapid response to consumer product health and safety issues.

Appendix

Table 1 New Active Ingredients Registered in 2012–2013

	Active Ingredient	End-Use Product (s)	Product Type	Registration Status	Product Category	Uses
1	Ametoctradin	ZAMPRO Fungicide	Fungicide	Full	Conventional Chemical	Brassica leafy vegetables: Broccoli; Broccoli, Chinese (gai lon); Broccoli raab (rapini); Brussel sprouts; Cabbage; Cabbage, Chinese (bok choy); Cabbage, Chinese (napa); Cabbage, Chinese mustard (gai choy); Cauliflower; Cavalo broccoli; Collards; Kale; Kohlrabi; Mizuna; Mustard greens; Mustard spinach; Rape greens Bulb vegetables: Garlic; Garlic, great headed; Leek; Onion, dry bulb; Onion, green; Onion, Welch; Shallot Cucurbit vegetables - Includes all types and hybrids of: Cantaloupe; Chinese waxgourd; Citron melon; Cucumber; Edible gourds; Gherkin; Muskmelon; Pumpkin; Summer squash; Watermelon; Winter squash; Zucchini; Momordica spp. (such as Balsam apple, Balsam pear, Bitter melon, Chinese cucumber) Fruiting vegetable group: Tomato; Eggplant; Ground cherry (Physalis spp) Pepino; Pepper (all varieties); Tomatillo Grapes Potatoes Hops Leafy vegetables: Celtuce; Cress (upland); Endive; Lettuce (head and leaf);
		BAS 650 00 F Fungicide	Fungicide	Full	Conventional Chemical	

	Active Ingredient	End-Use Product (s)	Product Type	Registration Status	Product Category	Uses
						Radicchio (red chicory)
2	Ammonia (Present as Ammonium Sulfate)	BUSAN 1215 Liquid Microbicide	Slimicide	Full	Antimicrobial	In influent water systems, in all process water systems used for the manufacture of paper and paperboard products, in industrial cooling towers, in recirculating cooling water systems, in ponds used for cooling purposes, in evaporative condensers, in airwashers equipped with mist eliminating systems and in reverse osmosis systems.
3	*Aureobasidium pullulans* Strain DSM 14941	BLOSSOM PROTECT	Bactericide	Full	Biopesticide	Bearing and non-bearing pome fruit (Crop Group 11-09 including Apple, Azarole, Crabapple, Mayhaw, Medlar, Pear, Asian pear, Quince, Tejocote and cultivars, varieties and/or hybrids of these commodities) Woody Rosaceae ornamentals
4	*Aureobasidium pullulans* Strain DSM 14940					
5	Azadirachtin	TreeAzin Systemic Insecticide	Insecticide	Full	Conventional Chemical	Trees in forest, woodlot, urban, and residential landscapes
6	*Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24	Taegro	Fungicide	Full	Biopesticide	Cyclamen (greenhouse) Wheat Lettuce (greenhouse and field) Tomato (greenhouse and field)
7	Camphor Oil	Mint-X Treated Plastic	Animal Repellent	Full	Biopesticide	Used in the manufacture of trash bags
8	Cornmint Oil					
9	Eucalyptus Oil					
10	Methyl Salicylate					
11	*Clavibacter michiganensis* (SPP *michiganensis*) Bacteriophage	AgriPhage-CMM	Bactericide	Full	Biopesticide	Greenhouse tomato
12	(Z,Z)-3,13-Octadecadien-1-ol	ISOMATE DWB	Insecticide	Full	Biopesticide	Pome fruits (Apple, Crabapple, Mayhaw, Pears, Quinces)

	Active Ingredient	End-Use Product (s)	Product Type	Registration Status	Product Category	Uses
13	(E,Z)-2,13-Octadecadien-1-ol					
14	(E,Z)-2,13-Octadecadien-1-yl Acetate					
15	Fluopyram	LUNA PRIVILEGE	Fungicide	Conditional	Conventional Chemical	Dried Shelled Bean, Bean (*Lupinus* spp., includes grain lupin, sweet lupin, white lupin, and white sweet lupin), Bean (*Phaseolus* spp., includes field bean, kidney bean, lima bean (dry), navy bean, pinto bean, tepary bean), Bean (*Vigna* spp., includes adzuki bean, blackeyed pea, catjang, Crowder pea, moth bean, mung bean, rice bean, Southern pea, Urd bean), Other Beans [Broad bean (dry), chickpea, Lablab bean, Lentil] Watermelon Wine grapes Peanut Apples Potato Strawberry Cherry (sweet and tart) Almond
		LUNA TRANQUILITY FUNGICIDE	Fungicide	Conditional	Conventional Chemical	Wine grapes Apples
		PROPULSE FUNGICIDE	Fungicide	Conditional	Conventional Chemical	Bean (*Lupinus* spp., includes grain lupin, sweet lupin, white lupin, and white sweet lupin), Bean (*Phaseolus* spp., includes field bean, kidney bean, lima bean, navy bean, pinto bean, tepary bean), Bean (*Vigna* spp., includes adzuki bean, blackeyed pea, catjang, Crowder pea, moth bean, mung bean, rice bean, southern pea, urd bean), Broad Bean (dry), Chickpea, Lablab Bean, Lentil

	Active Ingredient	End-Use Product (s)	Product Type	Registration Status	Product Category	Uses
16	Fluoxastrobin	EVITO 480 SC Fungicide	Fungicide	Conditional	Conventional Chemical	Wheat (Spring, Durum), Barley, Corn (Field, Seed, And Sweet), Soybean, Potato, Tomato, Pepper, Strawberry and Turf on sod farms, golf courses, lawns and landscape areas around residential, institutional, public, commercial and industrial buildings, parks, recreational areas and athletic fields
17	FLUXAPYROXAD	BAS 700 01 F FUNGICIDE	Fungicide	Full	Conventional Chemical	Crop Group 1C (Tuberous and Corm Vegetables) Sugarbeets Crop Group 6 (Legume Vegetables) Crop Group 8 (Fruiting Vegetables) Crop Group 11 (Pome Fruits) Crop Group 12 (Stone Fruits) Crop Group 15 (Cereal Grains) Crop Group 20 (Oilseeds) Peanuts
		BAS 700 04 F FUNGICIDE	Fungicide	Full	Conventional Chemical	
		BAS 700 02 F FUNGICIDE SEED TREATMENT	Fungicide	Full	Conventional Chemical	Soybean
		BAS 700 03 F FUNGICIDE SEED TREATMENT	Fungicide	Full	Conventional Chemical	
		BAS 703 01 F FUNGICIDE	Fungicide	Full	Conventional Chemical	Canola (including Rapeseed, Canola quality Brassica juncea) and Oilseed/condiment mustard, Flax, Sunflower, Soybeans, Field Peas, Lentils, Chickpeas, Fababean, Alfalfa for seed production Dry beans (except Soybean) Lupinus spp. (includes grain lupin, sweet lupin, white

	Active Ingredient	End-Use Product (s)	Product Type	Registration Status	Product Category	Uses
						lupin and white sweet lupin); Phaseolus spp. (includes field beans [dry common and coloured beans] such as kidney, lack, cranberry, pink, navy bean, pinto bean, tepary bean and lima bean [dry]); Vigna spp. (includes adzuki bean, blackeyed pea, catjang, cowpea, crowder pea, moth bean, mung bean, rice bean, southern pea, urd bean, broad or fababean [dry]) Edible Podded Legumes: Jack bean, pigeon pea, soybean (immature seed), sword bean; Phaseolus spp., runner bean, snap bean, wax bean; Vigna spp., asparagus bean, Chinese longbean, moth bean, yardlong bean; Pisum spp., dwarf pea, edible-podded pea, snowpea, sugar snap pea Succulent Shelled Pea & Bean: Pigeon pea; Phaseolus spp., lima bean, green; Vigna spp., blackeyed pea, cowpea, southern pea; Pisum spp., English pea, garden pea, green pea, broad bean
		PRIAXOR	Fungicide	Full	Conventional Chemical	Barley, Wheat (all types), Triticale, Rye, Corn (field, sweet, pop, seed types), Soybeans, Bluegrasses, fescues, ryegrasses grown for seed
18	Kasugamycin (Present as Hydrochloride Hydrate)	Kasumin 2L Bactericide	Bactericide	Full	Conventional Chemical	Fruiting Vegetables - Crop Group 8 (Greenhouse or Field) Pome Fruit - Crop Group 11-09 (Bearing and Nonbearing) Walnuts
19	Mono- and Dibasic Sodium, Potassium, and Ammonium Phosphites	PHOSTROL FUNGICIDE	Fungicide	Full	Biopesticide	Potatoes, Grapes, Strawberries Leafy greens: Head and leaf lettuce, upland cress, endive, radicchio (red chicory)

	Active Ingredient	End-Use Product (s)	Product Type	Registration Status	Product Category	Uses
						Head and Stem Brassica Crop Sub-Group 5A Black and red raspberry, wild raspberry and cultivars, varieties and/or hybrids of these Cucurbit vegetables: Chinese waxgourd, citron melon, cucumber, gherkin, edible gourd, *Momordica* spp., muskmelon, pumpkin, summer and winter squash, watermelon Tomato Crop Sub-Group 8-09A Ornamentals: Greenhouse-grown and outdoor bedding plants, potted plants and cut flowers Turf: Golf courses, sod farms, municipal, industrial and residential turf
20	N-ALKYL (40% C12, 50% C14, 10% C16) Dimethyl Benzyl Ammonium Saccharinate	Lysol Disinfectant Spray	Hard Surface Disinfectant and Sanitizer	Full	Antimicrobial	Sanitizer for use on fabric (soft porous surfaces)
21	Picoxystrobin	DuPont Acapela Fungicide	Fungicide	Full	Conventional Chemical	Dry Legumes (dry shelled beans and peas) chickpea (garbanzo); lentil; guar; lablab bean; lentil; broad bean (dry); pigeon pea; (Lupinus) grain lupin, sweet lupin, white lupin, white sweet lupin; (Phaseolus) field bean, kidney bean, lima bean, navy bean, pinto bean, tepary bean, (Vigna) adzuki bean, blackeyed pea, catjang, cowpea, crowder pea, moth bean, mung bean, rice bean, southern pea, urd bean, (Pisum) field pea Cereal Grains: Barley (*Hordeum* spp.), Oats (*Avena* spp.), Rye (*Secale cereale*), Triticale (*Triticum-Secale*

	Active Ingredient	End-Use Product (s)	Product Type	Registration Status	Product Category	Uses
						hybrids), Wheat (Triticum spp.) Corn, field corn, sweet corn, seed popcorn Soybean
22	*Pseudomonas fluorescens* Strain CL 145A	Zequanox	Molluscicide	Full	Biopesticide	For juvenile and adult mussel control, and veliger/larval stage settlement prevention control, in enclosed, semi-enclosed, and confined flowing water in infrastructure within dams and associated hydroelectric power plants
23	Pyroxasulfone	Pyroxasulfone 85 WG	Herbicide	Full	Conventional Chemical	Field corn
24	Sedaxane	CRUISER MAXX® VIBRANCE (TM) CEREALS Seed Treatment	Fungicide and Insecticide	Conditional	Conventional Chemical	Barley, Oats, Rye, Triticale, Winter wheat and Spring wheat
		VIBRANCE TM XL Seed Treatment	Fungicide	Conditional	Conventional Chemical	
		VIBRANCE 500FS Seed Treatment	Fungicide	Conditional	Conventional Chemical	Crop Group 15 (Cereals): barley, wheat, buckwheat, millet (pearl and proso, oats, rye, sorghum, teosinte, triticale, wild rice, corn Crop Subgroup 20A – Canola/Rapeseed Subgroup: Includes canola, borage, crambe, echium, flax seed, gold of pleasure, hare's ear mustard, lequerella, lunaria, meadowfoam, milkweed, mustard seed, oil radish, poppy seed, rapeseed, and cultivars and hybrids of the above crops. Legume Vegetables: Soybeans and Crop Subgroup 6C – Dried Shelled Peas and Beans, chickpeas, lentils and fava beans

	Active Ingredient	End-Use Product (s)	Product Type	Registration Status	Product Category	Uses
25	Sulfoxaflor	Closer SC Insecticide	Insecticide	Conditional	Conventional Chemical	Brassica (Cole) Leafy Vegetables (Crop Group 5) Grapes Leafy Vegetables (Except Brassica) (Crop Group 4) Pome Fruits (Crop Group 11-09) Root and Tuber Vegetables (Crop Group 1) Stone Fruits (Crop Group 12-09) Tree Nuts (Crop Group 14-11)
		Transform WG Insecticide	Insecticide	Conditional	Conventional Chemical	Barley and Wheat Canola (Rapeseed), Flax Seed and Similar Oilseeds (Crop Subgroup 20A): borage, crambe, echium, flax seed, gold of pleasure, hare's ear mustard, lesquerella, lunaria, milkweed, mustard seed, oil radish, rapeseed, sweet rocket, and cultivars, varieties and/or hybrids of these
26	Tetraconazole	METTLE 125 ME FUNGICIDE	Fungicide	Full	Conventional Chemical	Sugar Beets, Strawberries, Grapes and Gooseberries
27	*Trichoderma virens* Strain G-41	RootShield® PLUS WP Biological Fungicide	Fungicide	Full	Biopesticide	Outdoor container-grown nursery plants

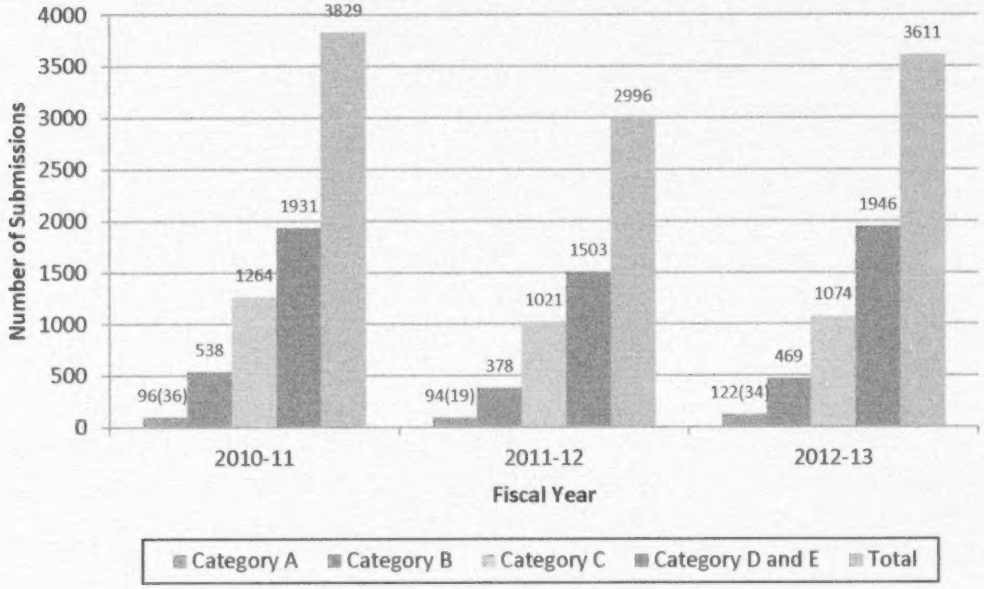
Table 2 Re-evaluation Decisions in 2012–2013

No.	Active Ingredient	Regulatory Publications	Summary of Decision or Proposed Decision (as contained in PRVD, RVD or REV note)
1	Boron	PRVD2012-03	**Proposed Decision:** Proposed continued registration for certain non-antisapstain uses of boron. For continuing uses, new risk-reduction measures are proposed to be included on the labels of certain products to further protect human health and the environment. Certain uses of boron are proposed for removal.
2	Denatonium Benzoate	RVD2012-06	**Final Decision:** Acceptable for continued registration. Mitigation includes new/revised label statements to further protect human health and the environment.
3	Ethalfluralin	RVD2012-09	**Final Decision:** Acceptable for continued registration. Mitigation includes new/revised label statements to protect human health and the environment.
4	Fenoxaprop-p-ethyl	RVD2012-07	**Final Decision:** Acceptable for continued registration. Mitigation includes new/revised label statements to protect human health and the environment.
5	Fluazifop-p-butyl	RVD2012-05	**Final Decision:** Acceptable for continued registration. Mitigation includes new/revised label statements to protect human health and the environment.
6	Linuron	PRVD2012-02	**Proposed Decision:** Proposed phase-out all uses of linuron. Based on available information the use of linuron products in accordance with the current label presents an unacceptable risk to health and environment.
7	Malathion	RVD2012-10	**Final Decision:** Acceptable for continued registration. Some uses were not supported by registrants and will be removed. Mitigation for the remaining uses includes new/revised label statements to protect human health and the environment.
8	MCPB	RVD2012-08	**Final Decision:** Acceptable for continued registration. Mitigation includes new/revised label statements to protect human health and the environment.
9	Nabam	RVD2012-03	**Final Decision:** Acceptable for continued registration. Mitigation measures include new/revised label amendments to further protect workers and the environment.
10	Poly[oxyethylene(dimethyliminio)ethylene(dimethylimino)ethylene Dichloride] (POD)	RVD2012-04	**Final Decision:** Acceptable for continued registration. Mitigation measures include new/revised label amendments to further protect workers and the environment.
11	Potassium and sodium dimethyldithiocarbamate salts	RVD2012-01	**Final Decision:** Acceptable for continued registration. Mitigation measures include new/revised label amendments to further protect workers and the environment.

Table 3 Product Submission Categories

Category A	Submissions to register new active ingredients and their companion end-use product(s); applications to add a major new use to a registered pesticide; submissions to establish a maximum residue limit for a previously non-assessed active ingredient; and submissions for user requested minor use registrations. Category A submissions require a full, supporting data package.
Category B	Submissions to amend a product label (for example, changes in application rates, timing of applications, new pests, changes to precautionary statements) or to change the product chemistry. Supporting data must be provided.
Category C	Submissions to register or amend a product label (add pest, use or change application rate) or change a formulation based on previously established precedents, or those that have reduced data requirements.
Category D	Submissions to register or amend products within particular programs such as the Import for Manufacture and Export, Own-Use Import, Grower Requested Own Use program, Master Copy, Private Label, User Requested Minor Use Label Expansion and renewal of registration.
Category E	Submissions for research authorizations and research notifications, when the research is carried out in Canada.

Figure 1 Number of Submissions Completed by the PMRA from 1 April 2010 to 31 March 2013



Trends and Limitations:

- Represents 12-month period
- Most category A and many category B submissions have >12-month timelines (therefore received in previous years)
- Increase in category A from previous years

Does not include pre-submission consultations.

Number of Submissions Completed includes Registered, Withdrawn and Rejected.

For Category A the number in ( ) is the number of new active ingredients completed.

Figure 2 Number of New Active Ingredients Registered by the PMRA from 1 April 2010 to 31 March 2013

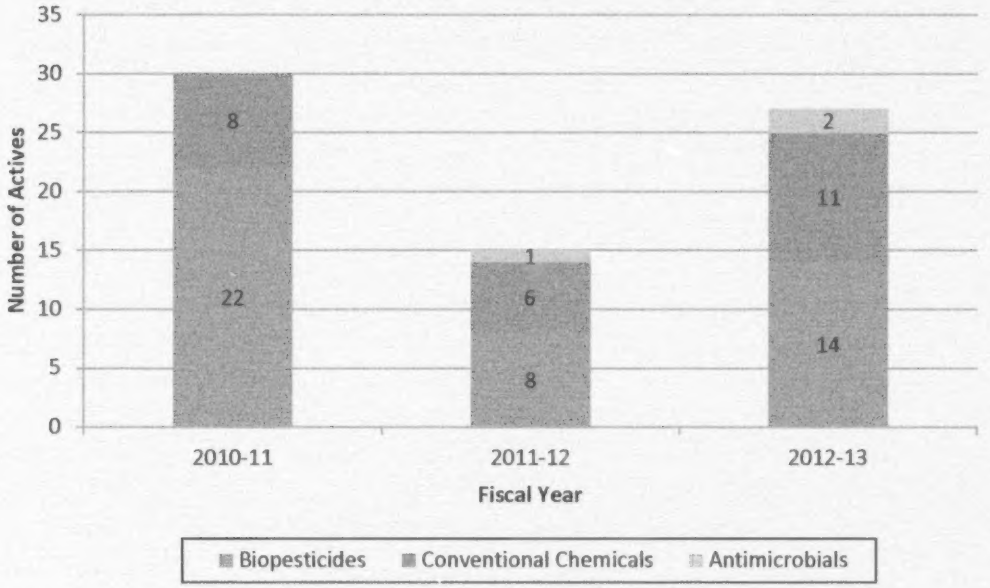


Figure 3 Performance Against Review Timelines for Category A, B and C Submissions Completed

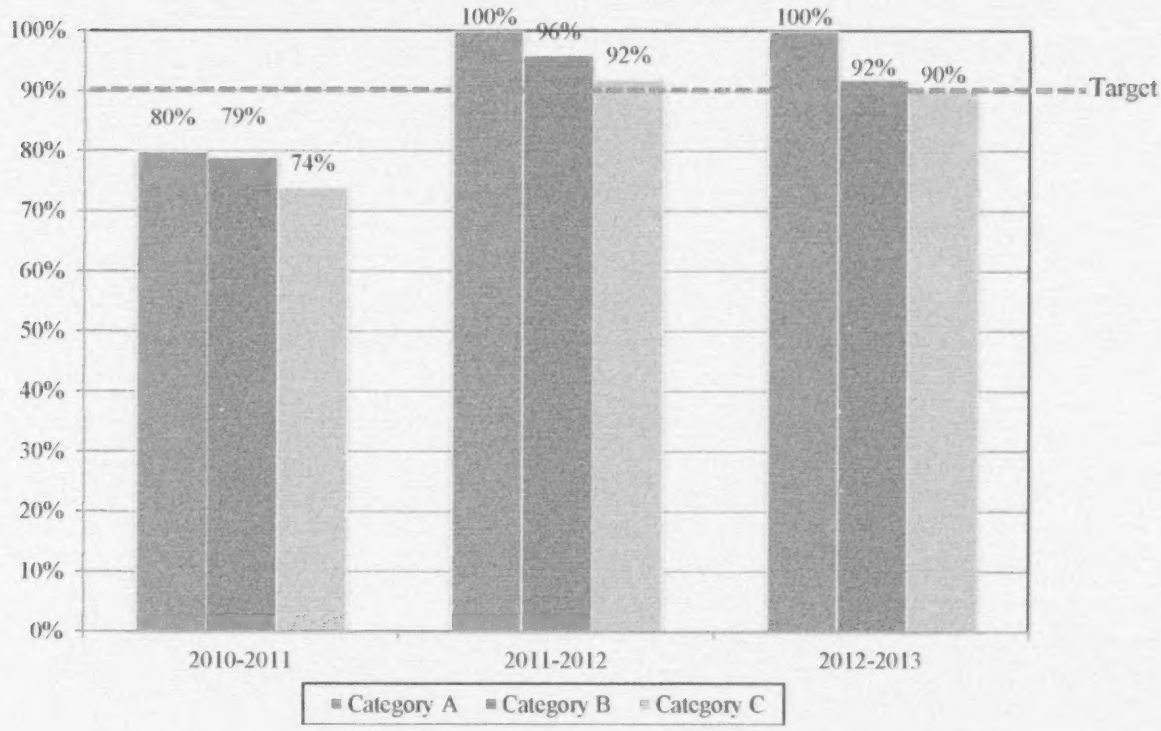


Table 4 Re-evaluation Activities as of 31 March 2013

	Final[1] Decisions	Proposed[2] Decisions	Pending[3] Publication	Total Decisions
Active ingredients addressed	11	6	1	18
Discontinued/withdrawn by registrant	0	0	0	0
Phase-out requested (or proposed for phase-out) as a result of PMRA review	0	1	0	1
Registration continued – label modifications	11	5	1	17
Registration continued – no label modifications	0	0	0	0

[1] The PMRA has finalized the re-evaluation decisions for these products (usually published in a Re-evaluation Decision).

[2] The PMRA has published the proposed decisions (usually in a Proposed Re-evaluation Decision).

[3] Assessments have been completed and decisions proposed, but the PMRA has not yet published the proposed decisions.

Table 5 Approved GROU Products

Grower Requested Own Use (GROU) is an initiative put in place by the PMRA to make it easier for Canadian growers to access less-expensive, equivalent pest control products available in the United States. Representatives of key grower associations sit on the GROU Nomination Committee and choose appropriate products for the program with input from member organizations. Thanks to this mechanism, growers with an approved import certificate can legally obtain the American version of a Canadian-registered product.

In 2012–2013, 20 products were available under the GROU Program:

- Elevate 50 WDG Fungicide (Pest Control Product #25900)
- Velpar L Herbicide (Pest Control Product #18197)
- FirstRate Herbicide (Pest Control Product #26697)
- Oracle Dicamba Agricultural Herbicide
- Apollo SC Ovicidal Miticide (Pest Control Product #21035)
- Agri-mek 1.9% EC Insecticide/Miticide (Pest Control Product #24551)
- Pursuit 240 (Pest Control Product #23844)
- Pursuit Herbicide (Pest Control Product #21537)
- B-Nine WSG (Pest Control Product #17465)
- SePRO A-Rest Solution (Pest Control Product #16393)
- SUMAGIC Plant Growth Regulator (Pest Control Product #25781)
- Bonzi Plant Growth Regulator (Pest Control Product #25453)
- Prowl 400 EC Herbicide (Pest Control Product #23439)
- Assure II Herbicide (Pest Control Product #25462)
- Reglone Desiccant (Pest Control Product #26396)
- Aatrex Liquid 480 (Pest Control Product #18450)
- Reflex Liquid Herbicide (Pest Control Product #24779)
- Roundup WeatherMax with Transorb 2 Technology Liquid Herbicide (Pest Control Product #27487)
- Banvel II Herbicide (Pest Control Product #23957)
- Basagran Liquid Herbicide (Pest Control Product #12221)